

U. S. ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Response to 30-day Error Correction Comments made by Dow AgroSciences (letter dated 2 November 2001) on EFED's Preliminary Risk Assessment

TO: Deanna Scher, Chemical Review Manager
Susan Lewis, Branch Chief
Reregistration Branch I
Special Review and Reregistration Division (7508C)

FROM: Christine Hartless, Wildlife Biologist, Environmental Risk Branch I
Amer Al-Mudallal, Chemist, Environmental Risk Branch I
Norman Birchfield, Biologist, on detail to Environmental Risk Branch IV
Environmental Fate and Effects Division (7507C)

THRU: Dana Spatz, Acting Branch Chief
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C)

EFED has reviewed Dow AgroSciences' (DAS) 30-day error correction comments on our preliminary risk assessment for oxyfluorfen. We have addressed these comments and any errors have been corrected in the attached risk assessment. Some of DAS's comments did not reflect mathematical or typographical errors. These comments went beyond 'error correction' and reflect different opinions and approaches in risk assessment methodology. These comments are noted below and will be addressed after the public comment period is completed.

Additional changes to the chapter were made to reflect the change in registration numbers and the registration of a new product (Goal 4F).

It is important to note that none of the corrections affected the overall risk conclusions.

Specific Responses to DAS Comments

Page 1, Cover Memo - The registrant does not agree that there is a potential for oxyfluorfen to be more toxic in the presence of intense sunlight than in standard guideline toxicity tests.

EFED does not consider the referenced statements made in the risk assessment to be an error. This comment will be addressed after the public comment period is concluded.

Page 2, Cover Memo - The registrant states that the requested raw data for the Aquatic Invertebrate Life Cycle study (MRID 921361-06) will be submitted and the study should be upgraded to "core."

EFED has not yet received the referenced raw data. The data will be reviewed after they are received and, if acceptable, the study will be upgraded to core.

Page 3 - Cover Memo - Submission of phototoxicity studies should be addressed as a research topic outside the reregistration process.

EFED does not consider the referenced statements made in the risk assessment to be an error. This comment will be addressed after the public comment period is concluded.

Page 3 - Cover Memo - For the estuarine/marine fish acute toxicity study (MRID 416988-01), no mortality was observed up to a mean-measured concentration of 170 µg/L. EFED used this value of 170 µg/L as an LC₅₀ and concluded that estuarine/marine fish were more sensitive than freshwater fish (with observed LC₅₀'s ranging from 200 to 410 µg/L).

EFED has modified its risk assessment to more appropriately reflect the submitted data. Modifications have been made in page 3 of the cover memo and in the relevant pages of the risk assessment document.

Page 6 - maximum application for non-bearing citrus should be 4.0 lbs ai/acre/year, not 6.0 lbs ai/acre/year.

EFED recognizes this typographical error and it has been corrected. This error only occurred in one place in the text of the document; correct application rates according to the label were used in all non-bearing citrus scenarios.

Page 10 - DAS states that two field studies conducted in MO and NC (MRIDs 94749 and 127936) were omitted in the discussion of aquatic Acute Risk LOC exceedences.

EFED recognizes that these studies were omitted from the discussion, however, this is not considered an error. EFED believes the studies cited provide only a very limited data useful in assessing risks associated with oxyfluorfen. Discussion of these studies will be included in the revised risk assessment chapter to be prepared after the public comment period.

Page 12 - DAS expressed concern about EFED's statements regarding the potential for phototoxic effects to birds and mammals in the environment.

EFED does not believe the statements included in the risk assessment chapter regarding the potential for phototoxic effects of oxyfluorfen in birds and mammals were incorrect. EFED will address DAS's comments during the public comment period.

Page 16 - DAS has proposed alternative input values for the PRZM/EXAMS modeling performed to estimate concentrations of oxyfluorfen for an aquatic ecological or a drinking water risk assessment.

EFED does not believe any errors were made in the PRZM/EXAMS modeling.

For the Tier II modeling for aquatic exposure and drinking water assessment, EFED used the most current Oregon apple scenario developed and QA/QC'd using the "Procedure for Conducting Quality Assurance and Quality Control of Existing and New PRZM Field and Orchard Crop Standard Scenarios" (2 August 2001). This document and the scenarios developed using this process are expected to be available on the EPA Office of Pesticide Programs website before the end of the calendar year.

For the chemical specific input parameters, EFED followed the guidance provided in "Guidance for Chemistry and Management Practice Input Parameters For Use in Modeling the Environmental Fate and Transport of Pesticides" (7 November 2000) developed by the Water Quality Tech Team in EFED. This parameter selection guidance has been developed to assist with the regulatory assessment of potential risk posed by pesticides to human health and to the aquatic environment. The choices made in developing input parameters reflect this particular use. When the parameter is highly variable, an upper bound estimate, based on the available fate data, has been used for the parameter. Whenever possible, each parameter has been related to relevant fate data, and as few default values as possible have been used. In some cases, rather than use a limiting default value, a parameter has been estimated from a similar related parameter with the addition of an uncertainty factor. To a lesser extent, we have attempted to avoid using extreme values (minima or maxima) from the fate data set. The input parameter guidance document reflects current practices which are in place at this time and will be updated, as necessary, to reflect improvements in the models and in our knowledge of fate and transport of pesticides. Limitations in the documentation for selecting each parameter have been identified where possible.

Page 17 - DAS has proposed alternative drinking water concentrations based on their modeling. These concentrations are approximately 65% lower than the concentrations proposed by EFED.

See comments related to page 16, above.

Page 17 - Monitoring data for oxyfluorfen are limited; however, DAS believes that the data are sufficient to use an estimate of 0.27 µg/L for a drinking water assessment. DAS also suggests

utilizing data obtained from a USEPA/USGS/USDA/ACPA interagency workgroup mini-pilot monitoring study.

EFED will re-evaluate all monitoring data and their relevance to drinking water concentrations at the end of the public comment period.

Page 19-20 - DAS stated that the correct quantity of Goal 2XL was 20,000 pounds (2600 gallons) and asserted that there was no evidence to claim that the spill had any effect on migrating salmon in the Columbia River. They also suggested that salmon spawning and migration was greater than average this year, suggesting that the spill had no effect on salmon spawning or migration.

EFED acknowledges that the correct estimated quantity of Goal 2XL in the spill was 20,000 pounds (2600 gallons), and this error will be corrected. The following sentence will also be modified as follows:

“This spill was estimated to cause a 35% decrease in the numbers of adult chinook salmon and a 26% decrease in the numbers of steelhead passing over the Dalles Dam the day immediately following the spill, relative to the day prior to the spill.”

EFED will evaluate any other data that is submitted between now and the end of the public comment period regarding changes in spawning and migration patterns of salmon near the spill.

Page 21, Table 5 and Page 23, Table 6 - DAS suggested modifying the aquatic EECs based on the proposed PRZM/EXAMS model output for Oregon apples.

See comments related to page 16.

Page 24 - DAS suggested modifying the aquatic EECs based on the proposed PRZM/EXAMS model output for Oregon apples. Also, DAS is submitting a toxicity study for Pseudokirchneriella (Selenastrum) which provides a NOEC for biomass and growth rate of $>2.9 \mu\text{g/L}$.

EFED believes the EECs provided in the risk assessment are correct. EFED will evaluate the changes in the PRZM/EXAMS input values proposed by DAS and determine if any changes to the scenario used by EFED are appropriate.

EFED welcomes the submission of additional data relevant to risks associated with oxyfluorfen use.

Page 25 - DAS states that since oxyfluorfen is one of the least mobile, most hydrophobic herbicides, concerns raised by aquatic plant LOC exceedences do not translate into adverse impacts. DAS also has the opinion that the cited nursery pond study has little relevance to other application sites or water bodies.

EFED had not made any mathematical or typographical errors in its statements. The comments will be addressed after the public comment period is concluded.

Page 26 - There is inconsistency in the citations of the Bergamaschi monitoring work discussed on page 16 and pages 26-27. DAS assumes the 0.27 µg/L maximum estimated dissolved concentration on page 27 of the EFED chapter is correct.

EFED has noted an error on page 26 in relation to the citation for Bergamaschi et al. The correct year for the citation should be 1997 not 1992. In addition EFED is clarifying the range of estimations concentrations. The concentration cited above by DAS (0.27 µg/L) corresponds to the highest *average* concentration estimated from samples collected at a single site: Vernalis California. The peak estimated concentration at Vernalis, based on four samples and using the same method used to estimate the average, is 0.82 µg/L.

EFED has reworded the paragraph on page 26 to the following:

Limited monitoring data also provide further information to the evaluation of environmental risk to aquatic organisms. Based on sampling during February 1992 in the San Joaquin River (at Vernalis, California), oxyfluorfen concentrations in suspended sediment ranged from 11.8 to 82.2 µg/L (Bergamaschi et al. 1997). Using a partitioning factor of 100 (see Appendix C), dissolved water concentrations are estimated to be between 0.12 and .82 µg/L. Using 0.82 µg/L as an EEC, the Acute Risk LOC was exceeded for aquatic plants (RQ = 2.8), but there were no acute LOC exceedences for freshwater and estuarine/marine fish (RQ < 0.01), freshwater invertebrates (RQ < 0.01), and estuarine invertebrates (RQ = 0.02). These concentrations of oxyfluorfen in water are comparable to concentrations expected in the standard farm pond based on PRZM/EXAMS modeling for California cole crops; however, they are lower than those expected based on PRZM/EXAMS modeling for California walnuts. Long term sampling at four sites in the San Joaquin River had estimated average concentrations in water ranging from 0.01 to 0.27 µg/L (Bergamaschi et al. 1997 and Appendix C), indicating a lower risk to aquatic organisms on average.

Page 27 - DAS states that the spill of Goal 2XL occurred on 22 August 2000.

EFED concurs and the typographical error has been corrected.

Page 27 - DAS comments on several exposure model uncertainties and an effect uncertainty in the aquatic assessment that were not addressed in the risk assessment chapter.

EFED does not consider this to be an mathematical or typographical error. This comment will be addressed after the public comment period is concluded.

Page 31 - DAS concurs that numerous deficiencies exist in the terrestrial plant guideline studies that have been submitted and reviewed. DAS has agreed to conduct repeat studies for seedling emergence and vegetative vigor. DAS expressed the opinion that conclusions from these studies are suspect because of the many deficiencies.

EFED welcomes the submission of additional data relevant to risks associated with oxyfluorfen use.

Page 31-32 - DAS states that incidents reported on non-target crops are not necessarily related to ecological effects.

DAS's comment does not reflect an error in the risk assessment. The comment will be addressed in the revised risk assessment after the completion of the public comment process.

Pages 32-34 - DAS contends that the highest one-day residue is an inappropriate exposure to a chronic ecotoxicological endpoint and proposes using the mean daily exposure over a 22 week period as the appropriate chronic EEC. DAS also comments that most sprayed vegetation would become unpalatable to terrestrial birds and mammals after 2 days. If another contact herbicide is added, such as glyphosate, the period of palatability may last up to 2 weeks. DAS also doubts that treated insects would live long enough to generate chronic exposure in most instances.

Current EFED guidance is to use the acute exposure EECs for the chronic exposure EECs (Guidance for Conducting Screening Level Avian Risk Assessments for Spray Applications of Pesticides, 7 July 2000). Several researchers have demonstrated that pesticide effects on avian reproduction are not simply a function of chronic exposure (references provided in guidance document). For example, reproduction in breeding bobwhite quail and mallard ducks can be affected by organophosphate insecticides with exposure periods as short as 8-10 days. In addition, many other compounds, including protoporphyrinogen oxidase inhibitors like oxyfluorfen, show reproductive effects to mammals after a single exposure. In lieu of other evidence, EFED assumes that a very short exposure to a pesticide can result in negative reproductive effects.

Pages 34-35 - DAS is concerned that EFED is predicting the likelihood of exposure using a Tier I screen for terrestrial plants.

EFED recognizes that the likelihood of exposure cannot be predicted with a Tier I screening model and does not make such conclusions in the risk assessment. The exposure models are used solely to assess magnitudes of exposure.

Pages 35-37 - DAS proposes alternative chronic RQ estimates for birds and mammals using a time-averaged predicted maximum residue. DAS suggests that chronic RQs for herbivorous animals need not be calculated since vegetation will be unpalatable after 2-14 days. DAS states that longevity of treated insects would probably be insufficient to provide chronic exposure.

See comments related to pages 32-34 above.

Page 38-39 - DAS questions whether a reduction of vegetative vigor by 25% can be linked to an actual ecological effect. DAS states that a 25% reduction in seedling emergence could be ecologically significant, but only in the context of a more definitive problem formulation.

DAS's comment does not reflect an error and will be considered during the public comment period.

Page 42 - DAS states that if the chronic RQs were calculated with time-weighted EECs, risks would be greatly reduced. DAS restates that chronic exposure to herbivores is eliminated and chronic risk to insectivores is reduced, based on the same reasons as provided by DAS in previous comments.

As stated earlier, current EFED guidance is to use acute EECs for chronic RQ calculation. Regarding this comment, there are no errors to correct.

Pages 43-44 - DAS concurs with the Agency that plants damaged by oxyfluorfen may recover. The lack of oxyfluorfen translocation within the plant is a limiting factor. DAS also states that rapid metabolism of oxyfluorfen allows injured plants to recover quickly, often with complete recovery within 2 weeks. DAS states that twice the application rate is required to cause 100% injury, when compared to the rate that causes 90% injury. DAS states that greenhouse/growth chamber data is a poor predictor of field effects because application rates to cause comparable injury typically differ by a factor of 3 to 10x between the greenhouse and the field. Finally, DAS cites AAPCO data for 1996-1998 during which there were no reported incidences of oxyfluorfen drift (out of 7595 reported drift incidences).

EFED is not aware of any errors in its assessment of risks to terrestrial plants. EFED will consider additional submitted data that will further refine the risk assessment.

Pages 80-82 - DAS has submitted alternative input parameter values for the IR Oregon apple PRZM/EXAMS scenario.

See comments related to page 16.

Other Changes to the Environmental Fate and Effects Division Chapter on Oxyfluorfen

Table 1, page 4, has been modified to include the conditional registration of Goal 4F (Reg. # 62719-447). The company names and registration numbers have been changed from Rohm & Haas to Dow AgroSciences.

Several statements regarding a toxicity study conducted on predacious mites using Goal 4F (MRID 452713-03) were modified to reflect the recent registration of this product in the United States. Changes occur on pages 12-13, 43, and 109.